

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION**

LLOYD BELL, Individually and
As Executor of the Estate of BETTY
WHITLEY BELL, Deceased,

Plaintiff,

v.

AMERICAN INTERNATIONAL
INDUSTRIES, et al.,

Defendants.

CASE NO. 1:17-CV-00111

**NON-PARTY NORTHWELL HEALTH, INC.’S RULE 72(a) OBJECTIONS TO
AND APPEAL FROM THE MAGISTRATE JUDGE’S FEBRUARY 25, 2021 ORDER**

COMES NOW non-party Northwell Health, Inc. (“Northwell”), pursuant to Local Rule 72.4, and respectfully files these Objections to and Appeal from the Magistrate Judge’s February 25, 2021 Order (“Objections”). Northwell specifically requests that this Court overturn the Magistrate Judge’s February 25, 2021 Order (the “Order”), ECF No. 309, and grant Northwell’s Motion to Intervene and Extend Protective Order (the “Motion”). ECF Nos. 256, 265.

As explained in more detail below, Northwell submits that its Motion should be granted and lodges the following specific objections to the Magistrate Judge’s Order:

1. It was clearly erroneous to deny Northwell’s Motion to Intervene on the basis that Northwell’s Motion is moot. Northwell’s Motion is not moot because the Plaintiff intends to offer Dr. Moline as an expert witness, and that issue remains unresolved.
2. It was clearly erroneous to deny Northwell’s Motion to Intervene on the basis that it was untimely. Northwell’s Motion was timely filed in the midst of ongoing

expert discovery—which is continuing as of the filing of these Objections—and Defendants will not be prejudiced if Northwell is permitted to intervene.

3. The Magistrate Judge’s analysis of the merits of Northwell’s Motion is clearly erroneous. The Magistrate Judge did not give sufficient credence to Northwell’s significant and unique interest in protecting the identity of research subjects in Institutional Review Board approved research studies and misconstrued the Plaintiff’s HIPAA authorization.

Northwell sought to intervene in this action for the limited purpose of seeking an extension of the existing protective order entered in this case on September 25, 2020 (the “Protective Order”). In its Motion, Northwell requested the extension of the Protective Order to preclude Defendants’ counsels from questioning Plaintiff’s expert witness, Dr. Jacqueline Moline, M.D. (“Dr. Moline”), regarding the identity of the patients in Dr. Moline’s peer-reviewed publication entitled, “Mesothelioma Associated with the Use of Cosmetic Talc” (the “Article”), including any documentation, analyses, or conclusions related to the Plaintiff. ECF No. 265 at 1.

On February 25, 2021, the Magistrate Judge denied Northwell’s Motion, finding that intervention was moot and, in the alternative, untimely. ECF No. 309 at 3-4. Additionally, the Order maintained that Northwell’s substantive claims regarding extending the Protective Order “fail[ed] on the merits” because Plaintiff raised the same arguments in September 2020 prior to the issuance of the Protective Order and because the Plaintiff consented to release of the information in this litigation. *Id.* at 5-8.

As set forth in more detail below, the Court should overturn the Magistrate Judge’s Order and grant Northwell’s Motion to Intervene for the purposes of extending the Protective Order. In

the alternative, the Court should remand the Motion to the Magistrate Judge for a hearing on the merits.

BACKGROUND

In 2019, Northwell physician, Dr. Moline, along with two colleagues, published the Article, which was based on an analysis of records associated with thirty-three individuals diagnosed with mesothelioma with no known asbestos exposure other than to cosmetic talcum powder. ECF No. 265 at 3. The Article concluded that asbestos-contaminated cosmetic talcum powders can cause mesothelioma and that treating clinicians should elicit a history of its usage in patients Id. As part of this research, Dr. Moline secured approval from Northwell’s Human Research Protection Program (“HRPP”) through its Institutional Review Board (“IRB”). Id. As part of the approval process, Dr. Moline made specific representations regarding the confidentiality and privacy of the research subjects, including that (1) she took confidentiality seriously and would take extensive measures to protect the participants’ identities; (2) no patient identifiers would be included in research-related summaries; (3) all protected health information (“PHI”) included in her review and the Article would be de-identified; (4) and the PHI would be stored in Northwell’s secure database. Id. at 4. Without these representations, the proposal would not have been in compliance with federal regulations and the IRB would not have approved Dr. Moline’s research proposal. Id. See The Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46, Subpart A (or, “The Common Rule”).

On August 20, 2020, Defendant American International Industries (“AII”) served Northwell with a subpoena for documents related to Dr. Moline and the Article. Id. at 5. Additionally, AII provided Northwell with a HIPAA Authorization signed by the executor of Plaintiff’s estate. Id. Northwell’s prior counsel produced to AII a spreadsheet listing the thirty-

three participants in the research study, with all names of the subjects, except Plaintiff's, redacted.

Id. After this disclosure, Plaintiff moved for a protective order and the parties in the case briefed the issue, which culminated in the Court granting the Protective Order, in part, in September 2020.

Pursuant to the Protective Order, the identities of the other thirty-two research subjects were to be protected, but the Plaintiff's participation in the research study was not to be protected. By virtue of the Court's limited ruling, Dr. Moline would be required to answer any questions regarding the Plaintiff's connection to the research study in violation of the Common Rule and IRB requirements of confidentiality and privacy.

STANDARD OF REVIEW

District courts review magistrate judges' rulings on non-dispositive motions, including motions to intervene, using a clearly erroneous standard. Fed. R. Civ. P. 72(a) ("The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law."). For a magistrate judge's order to be "clearly erroneous," the district court must find that, "although there is evidence to support it, on the entire evidence the reviewing court is left with the definite and firm conviction that a mistake has been committed." Smith v. N. Carolina Dep't of Safety, 2019 WL 3798457, at *1 (M.D.N.C. Aug. 13, 2019) quoting Faulconer v. C.I.R., 748 F.2d 890, 895 (4th Cir. 1984).

ARGUMENT

I. The Magistrate Judge's denial of Northwell's Motion to Intervene on the grounds of mootness and untimeliness is clearly erroneous.

Under Fed. R. Civ. P. 24(b), a non-party to an action may seek to intervene to expand or enter a protective order. See, Beckman Industries, Inc. v. International Ins. Co., 966 F.2d 470, 472 (9th Cir. 1992). In determining whether to grant such a motion to intervene, the Court considers whether the motion is timely and "whether the intervention will unduly delay or prejudice the

adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3); see also Students for Fair Admissions Inc. v. Univ. of North Carolina, 319 F.R.D. 490, 494 (M.D.N.C. 2017). Additionally, the Fourth Circuit has a "policy favoring 'liberal intervention' and preventing the 'problem of absent interested parties.'" Id. at 493 quoting, Friend v. REMAC Am., Inc., 2014 WL 2440438, at *1 (N.D. W. Va. May 30, 2014); see also Feller v. Brock, 802 F.2d 722, 729 (4th Cir. 1986). In this matter, the Magistrate Judge clearly erred by finding that Northwell's motion to intervene was moot and, in the alternative, untimely. Additionally, the Magistrate Judge did not fully consider the Fourth Circuit's policy in favor of liberally allowing intervention. The Court should overturn the Order and allow Northwell to intervene for the sole purpose of moving to extend the Protective Order. Alternatively, the Court should remand the Motion to the Magistrate Judge for a hearing on the merits.

a. Northwell's Motion is not moot because Plaintiff intends to offer Dr. Moline as an expert witness.

In the Order, the Magistrate Judge maintained that Northwell's Motion is moot because the Plaintiff did not make Dr. Moline available for a deposition prior to a court-ordered deadline. ECF No. 309 at 3. The Magistrate Judge reasoned that the passage of the deadline indicated that the Plaintiff no longer planned to offer Dr. Moline as an expert witness and, therefore, Northwell no longer had a basis to intervene. Id. However, the Plaintiff and Defendants have since filed a Joint Status Report on March 5, 2021, which states, in applicable part, "Plaintiff intends to offer Dr. Jacqueline Moline for completion of her deposition, on a date to be determined." ECF No. 312 at 11. Although the Defendants objected to the inclusion of Dr. Moline as an expert in the Joint Status Report, the Plaintiff clearly stated the intention to "fil[e] a motion for leave to present Dr. Moline for deposition" pending the final resolution of Northwell's Motion. Id. Contrary to the

Magistrate Judge’s finding, Plaintiff has not elected to withdraw Dr. Moline as an expert witness in this case and Northwell’s Motion is not moot.

b. Northwell’s Motion to Intervene is timely and Defendants would not be prejudiced if Northwell was permitted to intervene.

When considering whether a motion to intervene is timely, the Court considers three factors: “(1) how far the suit has progressed; (2) the prejudice that delay might cause other parties; and (3) the reason for the tardiness in moving to intervene.” Students for Fair Admissions Inc., 319 F.R.D. at 494 (citation omitted). The Magistrate Judge’s finding that Northwell’s Motion is untimely is clearly erroneous based on a consideration of these factors.

When considering the first factor, the Magistrate Judge’s Order narrowly focuses on the passage of time since the September 2020 Protective Order and subsequent discovery deadlines, ignoring the fact that the passage of time is “only one factor to be considered in light of all the circumstances.” Wright v. Krispy Kreme Doughnuts, Inc., 231 F.R.D. 475, 478 (M.D.N.C. 2005), quoting Spring Constr. Co. v. Harris, 614 F.2d 374, 377 (4th Cir. 1980). The Magistrate Judge also fails to consider the underlying purpose behind this requirement, which is to “prevent a tardy intervenor from derailing a lawsuit within sight of the terminal.” Students for Fair Admissions Inc., 319 F.R.D. at 494 (citation omitted). In this case, the “terminal” is not within sight. Specifically, expert witness discovery in this case is still very much ongoing. Based on deadlines proposed by both parties in their Joint Motion to Extend Time for Expert Depositions—which were granted by the Magistrate Judge on March 9, 2021—depositions may continue in this case until at least April 27, 2021. See ECF No. 280. Additionally, Defendant AII filed a Motion to Compel Discovery on February 27, 2021, which is still pending. ECF No. 310. Further, the trial in this case is not scheduled until October 4, 2021. All of these facts indicate that the “terminal” of discovery is not within sight (let alone the “terminal” of the case as a whole).

Second, the Magistrate Judge incorrectly found that Northwell's intervention would prejudice the parties to this case. In the Order, the Magistrate Judge stated that allowing intervention "would require the Parties to effectively relitigate issues the Court resolved in September, stall progression of the case, and potentially delay trial, which would prejudice the Parties." ECF No. 309 at 4. Contrary to the Magistrate Judge's finding, allowing Northwell to intervene for the sole purpose of extending the Protective Order while expert discovery is ongoing would not prejudice the parties to this case. As discussed above, the parties themselves have requested modifications to discovery deadlines subsequent to the filing of Northwell's Motion, including deposition deadlines as late as April 27, 2021, which the Magistrate Judge granted on March 9, 2021. ECF No. 280. Furthermore, with trial currently set for October 4, 2021 and the first pre-trial deadline set for September 3, 2021, it is unlikely that Northwell's intervention would delay trial, given the limited nature of the intervention and ongoing expert witness discovery.

Finally, the Magistrate Judge erred in not fully considering Northwell's reason for filing the Motion three months after the September 2020 hearing. In August 2020, Northwell received a subpoena from AII for records relating to Dr. Moline's research study. ECF No. 274 at 9. One month later in September 2020, Northwell's former counsel erroneously produced documentation indicating that the Plaintiff was one of the subjects in Dr. Moline's study. *Id.* After Northwell became aware of the disclosure, it worked to secure new counsel for the purposes of filing the Motion and protecting the critical confidentiality interests related to Dr. Moline's research study and Northwell's IRB process. ECF No. 284 at 3.

Under the liberal standard for intervention articulated by the Fourth Circuit, the Magistrate Judge's denial of Northwell's Motion, which was timely and would not prejudice the parties to this litigation, was clearly erroneous. For instance, in *Feller*, the Fourth Circuit held that "liberal

intervention is desirable to dispose of as much of a controversy involving as many apparently concerned persons as is compatible with efficiency and due process.” 802 F.2d at 729. In this case and as discussed above, it is unlikely that Northwell’s intervention would significantly delay the proceedings or prejudice the other parties. As such, under the Fourth Circuit’s liberal intervention standard, the Court should grant Northwell’s Motion.

II. The Magistrate Judge’s analysis of the merits of Northwell’s Motion is clearly erroneous.

In the Order, the Magistrate Judge erroneously found that Northwell’s argument for extending the Protective Order would fail on the merits because Northwell’s arguments would “not change [the Court’s] ultimate analysis.” ECF No. 309 at 6. In drawing this conclusion, **the Magistrate Judge did not give sufficient credence to Northwell’s significant and unique interest in protecting the identity of research subjects in IRB-approved research studies and misconstrued the Plaintiff’s HIPAA authorization.**

As discussed in more detail in Northwell’s Motion, Northwell, and other similarly situated research institutions, must follow the directives of The Common Rule, a federal policy to protect the safety, privacy, and confidentiality of research subjects. ECF No. 265. Under the Common Rule, Northwell researchers, such as Dr. Moline, must submit proposals to the IRB which include adequate protections for the privacy of the research subjects and the confidentiality of health data. 45 C.F.R. § 46.111. By requiring these protections, the IRB review process and The Common Rule aim to balance the benefits of the research to the general public with the research subject’s right to privacy and confidentiality. **Under The Common Rule, Dr. Moline is required to protect the confidentiality of research subjects unless, here, the Court makes a finding that the Defendants’ purported need to question Dr. Moline about the Plaintiff’s participation in the research study outweighs scientific and societal interests, including confidentiality and privacy requirements.** See,

e.g., Cusumano v. Microsoft Corp., 162 F.3d 708, 716 (1st Cir. 1998) (holding that “courts must balance the potential harm to the free flow of information that might result against the asserted need for the requested information”), quoting Bruno & Stillman, Inc. v. Globe Newspaper Co., 633 F.2d 583, 585-586 (1st Cir. 1980). In her ruling, the Magistrate Judge did not appropriately consider the legal directives of The Common Rule and bedrock federal policy surrounding the IRB process, which clearly outweigh the Defendants’ need to ask Dr. Moline a very narrow set of deposition questions. ECF No. 309 at 5-8.

Additionally, the Magistrate Judge misconstrues the Plaintiff’s HIPAA authorization, which was submitted to Northwell by Defendant AII. Id. at 7-8. The HIPAA authorization provided authorization to release the Plaintiff’s medical records; however, the information regarding the Plaintiff’s participation in Dr. Moline’s study was not a part of her medical record. ECF No. 179 at 3-5. The information was mistakenly produced by Northwell’s previous counsel and was not covered by the HIPAA authorization. As such, the Magistrate Judge clearly erred in placing undue weight on the narrow HIPAA authorization, at the expense of fully considering the bedrock requirements—and universally accepted norms—of The Common Rule and the IRB review process. ECF No. 309 at 7-8.

CONCLUSION

For the foregoing reasons, Northwell respectfully requests that the Court overturn the Magistrate Judge’s Order and grant Northwell’s Motion. In the alternative, Northwell respectfully requests that the Court remand the Motion to the Magistrate Judge for a hearing on the merits.

This the 11th day of March, 2021.

/s/ John H. Lawrence
John H. Lawrence
N.C. State Bar No. 45462
Steven G. Pine
N.C. State Bar No. 44705

K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
Telephone: (919) 466-1112
john.lawrence@klgates.com
steve.pine@klgates.com

ATTORNEYS FOR NORTHWELL

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 11, 2021, the foregoing Objections were filed via ECF filing, which will serve all counsel of record in the above-referenced matter.

This the 11th day of March, 2021.

/s/ John H. Lawrence
John H. Lawrence
N.C. State Bar No. 45462
Steven G. Pine
N.C. State Bar No. 44705

K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
Telephone: (919) 466-1112
john.lawrence@klgates.com
steve.pine@klgates.com

ATTORNEYS FOR NORTHWELL

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/s/ John H. Lawrence
John H. Lawrence